

REMARKS

Claim 1 has been amended to recite a "powder or granule composition consisting of...." Support for this amendment is found in the specification at, for example, page 1, lines 16-22 and page 2, lines 1-4; and in Examples 1 and 3.

Claims 2, 9, 12, and 13 have been cancelled, without prejudice.

Claim 8 has been amended to recite a "compressed tablet formed from a powder or granule composition consisting of..." and to incorporate the limitation of claim 9, which has been cancelled. Support for this amendment is found in the specification at, for example, page 2, lines 5-8; page 2, lines 24-27; and page 4, lines 4-9; and in original claim 9. See, *In re Gardner*, 177 USPQ 396, 397 (CCPA 1973) and MPEP §§ 608.01(o) and (l).

Claims 10 and 11 have been amended to depend from claim 8.

It is submitted that no new matter has been introduced by the foregoing amendments. Approval and entry of the amendments are respectfully solicited.

Rejection under 35 USC § 103

Claims 1-13 and 22-34 were rejected solely under 35 USC §103(a) as being unpatentable over Schmidt *et al.* U.S. Patent No. 4,605,666 ("Schmidt"), "and, if necessary," further in view of Newlin *et al.*, U.S. Patent No. 3,615,591 ("Newlin"), Chiralt *et al.*, 1999 (IFT Annual Meeting) ("Chiralt") and Hussaini *et al.*, ("A Guide to Halal Food Selection", 1993) ("Hussaini"). (Paper No. 11 at 3.)

For the reasons set forth below the rejection, respectfully is traversed.

Schmidt discloses a powder containing a water-soluble vitamin prepared by spray drying an aqueous slurry of the vitamin and a binder, a lubricant, and optionally an adsorbent and an additional excipient. (Col. 1, line 52 - Col. 2, line 54).

Newlin discloses a method of making "a peanut butter-jelly product so that not only is there no whitening or dark color penetration on the peanut butter, but also there is no surface discoloration of the peanut butter at the peanut butter-jelly interface." (Abstract.)

Chiralt discloses the "combined vacuum impregnation-osmotic dehydration in cryoprotection of apple." (Title.) Chiralt discloses that "[c]hanges in sample color ... after the freezing-thawing process were quantified to evaluate the cryopreservative effect of the VI-OD treatments." (Abstract.) "The most effective pretreatments in order to preserve sample color were those involving VI with pectin, where no significant browning was detected in apple samples after thawing." (*Id.*)

Hussaini discloses the "Islamic Status for the Permissibility of Various Food Additives." (Title.) Hussaini discloses that pectin is used as a "suspending agent, [and] improves colour." (Page 3, No. 56.)

The Examiner asserted only that "[t]his rejection is analogous to the original rejection." (Paper No. 11 at 3.) Accordingly, the original rejection (Paper No. 9) is summarized below.

In making the earlier rejection, the Examiner asserted that Schmidt discloses "a powder or tablet composition, comprising a water-soluble vitamin (i.e., sodium ascorbate, ascorbic acid, calcium ascorbate, etc...); a binder (i.e., microcrystalline cellulose, etc...); a lubricant (i.e., stearic acid, magnesium stearate,

calcium stearate, etc...) and an excipient (i.e., pectin, starch, etc...)." (Paper No. 9 at 3.) The Examiner further asserted that Schmidt "discloses that 'the components described herein are added in amounts such that the final powder formed will contain at least 80% (preferably at least 90) percent by weight of the water soluble vitamin, less than 15 (preferably less than 9) percent by weight of binder ... 0.2 to 5 percent by weight of the lubricant and less than 3 percent of other excipients ... those skilled in the art may discover better proportions with them and for specific purposes'." (*Id.* at 3-4.)

The Examiner acknowledged, however, that "Schmidt differs from the claimed invention in 1) the specific amounts of pectin in the composition, about 0.1 to about 10%, more specifically about 0.5 to 5%, based on the total weight of the composition; 2) 95-99% by weight of L-ascorbic acid and or a pharmaceutically acceptable salt; 3) the use of citrus pectin; and 4) the functional characteristic of pectin as a binder." (*Id.* at 4.)

To fill the acknowledged gap, the Examiner relied upon either Newlin or Chiralt as disclosing "the use of pectin as an effective anti-browning agent," and Hussaini as disclosing "the use of pectin as an effective color-improving agent." (*Id.*)

The Examiner then asserted that Schmidt "makes clear that the selection of secondary ingredients such as microcrystalline cellulose, stearic acid or magnesium stearate and pectin in a vitamin C (e.g., sodium ascorbate and ascorbic acid) powder or tablet is old and well know in the art," and that "optimization of amounts of known active and secondary ingredient(s) in a composition is well considered within the skill of the artisan." (*Id.*)

The Examiner also asserted that "[o]ne having ordinary skill in the art would have been ***motivated to employ*** pectin in vitamin C composition such that ***the stability of color of the claimed composition would be significantly improved,***" and that one would have been "***motivated to select*** well known anti-browning agent or color improving agent such as ***pectin to prevent browning or improve coloring of claimed composition*** containing L-ascorbic acid and/or its salts." (*Id.*)

The Examiner then concluded "the references make obvious the claimed invention" and that "the selection of citrus pectin among pectins is well considered within the skill of the artisan, absent evidence to the contrary." (*Id.* at 4-5.)

Initially, we note that the rejection is equivocal. The rejection asserts that claims 1-13 and 22-34 are rejected over Schmidt "and, if necessary," further in view of Newlin, Chiralt, and Hussaini. It is unclear if the Examiner is making a single reference rejection (Schmidt alone) or a combination rejection (Schmidt, in view of Newlin, Chiralt, and Hussaini). It is respectfully submitted that the PTO bears the burden to clearly and unambiguously provide notice to the Applicant of the basis for rejecting all claims. MPEP § 706.02(j) (8th Ed., Rev. 1, February 2003 pp. 700-44 to 700-45). When, as here, a rejection is ambiguous or equivocal, the applicant is placed in the unfair and prejudicial position of having to guess at the rejection. Accordingly, for this reason alone the rejection should be withdrawn or a new non-final action issued that unambiguously identifies the rejection.¹

¹ In an effort to further prosecution, we address the rejection as if the Examiner rejected the claims 1-13 and 22-34 over Schmidt in view of Newlin, Chiralt, and Hussaini.

As is well settled, a rejection under § 103 must demonstrate **where** in the cited documents there was a suggestion which would have “strongly motivated” one to carry out the invention as claimed. *Ex parte Graselli*, 231 USPQ 393, 394 (Bd. App. 1986). The type of motivation which would have “**impelled**” one to do so (*Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993)), and the type of suggestion that the changes “**should**” be made. *Ex parte Markowitz*, 143 USPQ 303, 305 (Bd. App. 1964). The factual inquiry whether to combine documents must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion to combine “**must be based on objective evidence of record**.” *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

As we noted in our Previous Response², the discussion of the secondary documents reads in its entirety: “Either Newlin or Chiralt teaches the use of pectin as an effective anti-browning agent. Hussaini teaches the use of pectin as an effective color-improving agent.” (Paper No. 9 at 4.) These assertions identify nothing in Schmidt or the secondary documents that discloses or suggests their combination to arrive at the claimed invention.

In response to this argument, the Examiner asserted only that “Examiner strongly disagrees. As evidenced by reference cited in Paper 9 (“Total C Product Information Brochure, www.nutripeak.com, 1998), the product comprising vitamin C and pectin is well known in the art.” However, a review of the document reveals that the Examiner has confused a copyright notice on the website with the publication date of

² See RESPONSE TO OFFICE ACTION INCLUDING AMENDMENT dated September 27, 2002 (“Previous Response”)

the brochure he relies upon. The brochure was printed on February 28, 2002, at 12:01 p.m., according to the notation found at the bottom right corner of the document. The copyright notice states: "© 1998-2001 Nutripeak.com, All rights reserved No portion of **Nutripeak.com** may be duplicated, redistributed or manipulated in any form." In view of the foregoing, the Examiner has not met his burden to show that the printed publication he relies on is prior art to the present application which was filed on December 15, 2000, fourteen months prior to the apparent publication date of the brochure. Accordingly, the Examiner's sole basis for "strongly disagreeing" with our comments is unavailable to him. In the absence of any other data or technical reasoning, the rejection must be withdrawn.

The rejection also uses the wrong standard for determining obviousness. The rejection relies upon "***motivated to employ***" and "***motivated to select***" standards that are not found in the statute or precedential authority. As previously noted, an Examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would ***impel*** one skilled in the art to do what the patent applicant has done. *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). We further note that the Examiner has relied on the earlier rejection and offered no response to this argument, and the argument therefore stands un rebutted. Accordingly, the rejection is insufficient as a matter of law, and should be withdrawn for this reason also.

We also noted that there is a factual gap in the earlier rejection in that it does not identify why one would look to food additive disclosures to solve a binding problem for tableting water-soluble vitamin compositions. Schmidt discloses a powder

containing a water-soluble vitamin, for use in making vitamin tablets. However, all of the secondary documents disclose the use of pectin in food products: Newlin discloses a peanut butter-jelly composition; Chiralt discloses a vacuum impregnated-osmotically dehydrated apple; and Hussaini discloses the use of various food additives in Islamic foods. The rejection identifies no disclosure or suggestion in any of the cited documents that food additives of the secondary documents would be useful in making the tableting compositions of Schmidt. And, the rejection does not identify where in the secondary documents there is a disclosure or suggestion to use water-soluble vitamins.

Further, the previous rejection concedes that Schmidt fails to disclose the use of citrus pectin. The rejection merely asserts that "the selection of citrus pectin among pectins is **well considered** within the skill of the artisan." (Paper 9 at 5.) Once again we note, "well considered" is not the proper standard under § 103, and even if it were, the rejection fails to identify where, in any of the cited documents, there is a disclosure or suggestion as to use of citrus pectin in the manner claimed.

The Examiner impliedly acknowledges these gaps by attempting to fill them with Hill, U.S. Patent No. 3,946,110 ("Hill"). The Examiner asserted that Hill discloses "the use of pectin (e.g. citrus pectin) in preparing medicinal compositions (e.g., tablet) is well recognized in the art." (Paper No. 11 at 4.)

Although, Hill has been made of record, the Examiner's rejection does not include Hill. Apparently, the Examiner is relying on Hill as proof of the state-of-the-art prior to the effective filing date of the present application. The problem with the Examiner's reliance on Hill is that the only active ingredient, or "medicament," disclosed or exemplified in Hill is acetylsalicyclic acid ("aspirin"). Hill does not provide data or

technical reasoning to suggest that acetylsalicylic acid would behave in a similar manner as ascorbic acid when combined with pectin. Thus, the Examiner's reliance on Hill to support the rejection is misplaced.

Accordingly, the rejection contains a factual gap because it does not identify why one would look to food additive disclosures to solve a binding problem for tableting water-soluble vitamin compositions. For this additional reason, the rejection is factually deficient and should be withdrawn.

In addition, the Examiner concedes that "the cited [documents] provide no evidence in regards to how one would modify the pectin levels to achieve the presently claimed binding properties." (Paper 11 at 3.) Indeed, as we noted in our Previous Response, the cited documents at best suggest optimizing color stabilization. And, the rejection provides no evidence that optimizing color stability would lead to the presently claimed pectin ranges. In response the Examiner asserted that "such property or characteristic must be inherent to the pectin. Therefore, the claimed composition is still properly rejected by a reference, even if the reference does not address or acknowledge this property." (Paper No. 11 at 3-4.)

As is well settled, an Examiner's belief or conjecture is no substitute for statutory prior art. *In re Kratz*, 201 USPQ 71, 76 (CCPA 1979) *citing*, *In re Antonie*, 195 USPQ 6 (CCPA 1977). ("We have previously rejected the argument that undirected skill of one in the pertinent art is an adequate substitute for statutory prior art.") Moreover, obviousness **must** be based upon facts, "cold hard facts." *In re Freed*, 165 USPQ 570, 571-72 (CCPA 1970). When a conclusion of obviousness is not based upon facts, it cannot stand. *Ex parte Saceman*, 27 USPQ2d 1472, 1474 (BPAI 1993).

However, conjecture is all that the Examiner has offered in this instance. If the Examiner wishes to rely on the alleged inherency of the binding properties of pectin, he must provide evidence in the form of statutory prior art that demonstrates that optimizing pectin levels for color stability would inevitably lead to the pectin levels recited herein having the same binding properties of the claim. Absent such evidence, the rejection is based on the unfounded, if strongly worded, conclusion of the Examiner. Simply stated, this is not the stuff of a *prima facie* rejection under § 103. The rejection has substituted conjecture as to what one skilled in the art would believe for the required statutory reference, for this additional reason the rejection should be withdrawn.

With a view toward furthering prosecution, however, claims 1 and 8 have been amended to recite the transitional phrase "consisting of." Nothing in the cited documents, alone or in combination, discloses or suggests compositions that pectin alone is sufficient to act as a binder for L-ascorbic acid and/or a pharmaceutically acceptable salt thereof. In view of the foregoing, it is respectfully submitted that the rejection of claims 1-13 has been rendered moot.

Moreover, in the Previous Response, claims 22-34 were added. Independent claims 22 and 29 recite that the composition has a compressibility that is superior to the compressibility of the same composition having a standard binder (e.g., starch or hydroxypropylmethylcellulose (HPMC)) in place of the pectin binder. Claims 22-34 were entered by the Examiner. (Paper No. 11 at 2.)

Claims 22-34 have been included in the current rejection. However, there is absolutely no discussion of these claims in the pending Office Action. The

Examiner's statement that "[t]his rejection analogous to the original rejection," offers nothing in response to the inclusion of these claims in the application. The original rejection could not have addressed these claims because they were added after that rejection had been made. In short, the Examiner has not actually considered claims 22-34. But that was his burden.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, ***the prior art reference (or references when combined) must teach or suggest all the claim limitations.*** The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. MPEP 2142 (8th Ed., Rev. 1, February 2003 p. 2100-124).

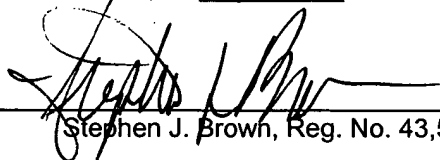
The rejection fails to acknowledge, much less identify any disclosure or suggestion in any of the cited documents that pectin, in the amount recited in claims 22-34, would produce the superior compressibility claimed.³ (See e.g., Examples 1-4 comparing the compressibility of a composition having solely a pectin binder to a conventional composition having a HPMC binder). Accordingly, the rejection of claims 22-34 is both legally and factually deficient and must be withdrawn.

³ As discussed above, the Examiner's conjecture as to the inherency of pectin's binding properties adds no evidence of record to support the rejection.

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For the reasons set forth above, entry of the amendments, withdrawal of the rejection, and allowance of the claims are respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

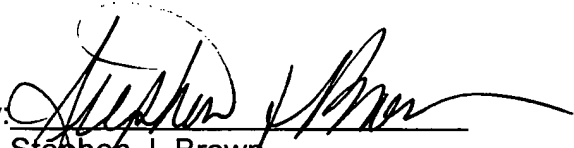
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